



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,464	07/29/2003	Jon Elliot Adler	100337/54260US	4703

23911 7590 09/06/2006

CROWELL & MORING LLP  
INTELLECTUAL PROPERTY GROUP  
P.O. BOX 14300  
WASHINGTON, DC 20044-4300

EXAMINER
----------

HOWARD, ZACHARY C

ART UNIT	PAPER NUMBER
----------	--------------

1646

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/628,464

Applicant(s)

ADLER ET AL.

Examiner

Zachary C. Howard

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 68-92 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 68-92 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1646

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 6/22/06 has been entered.

### ***Status of Application, Amendments and/or Claims***

The amendment of 6/22/06 has been entered in full. Claims 68 and 71 are amended.

Claims 68-92 are under consideration in the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Withdrawn Objections and/or Rejections***

The objection to claims 68 and 71 at pg 2 of the 2/22/06 Office Action is *withdrawn* in view of Applicants' amendments to the claims.

### ***Maintained Objections and/or Rejections***

#### ***Claim Rejections - 35 USC § 101, utility***

Claims 68-92 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. This rejection was set forth at pg 3-4 of the 2/22/06 Office Action.

In the 6/22/06 response, Applicants argue that "[t]his RCE request is submitted so that the Examiner will consider the functional data referenced in the prior Affidavit by Mark Zoller. As attested to therein, this data (contained in Figure 2) substantiates that

Art Unit: 1646

hT2R76 is a bitter taste receptor as correctly disclosed in the as-filed specification and specifically responds to the bitter ligands brucine and PROP. As indicated previously, PROP is among the bitter ligands disclosed in the as-filed specification that was indicated to be a ligand that potentially would specifically activate hT2R76."

Applicants' arguments have been fully considered but are not found persuasive. As set forth previously at pg 3-4 of the 2/22/06 Office Action, the affidavit under 37 CFR 1.132 filed 9/30/05 is insufficient to overcome the rejection of claim 68-92 based upon lack of utility under 35 USC 101. The affidavit states that PROP and brucine, but not other bitter ligands, specifically activate hT2R76 expressed in HEK-293 cells. This activation is stated to result in detectable changes in intracellular calcium changes and the results are stated to be contained in Figure 2 attached to the affidavit. However, there is no Figure 2 attached to the affidavit provided to the Examiner. The Examiner notes that the 6/22/06 response also does not include a copy of the affidavit. Therefore, the evidence in support of utility is not found persuasive because Figure 2 has not provided for independent evaluation by the Examiner. Therefore, the utility rejection is maintained for reasons set forth previously. The proposed uses of the claimed invention are starting points for further research and investigation by the skilled artisan to determine potential practical uses of the claimed nucleic acids.

In the 6/22/06 response, Applicants additionally state that "[a]pplicants provide a copy of Board of Appeals Decision in US Serial No. 09/825,882 wherein the Board of Appeals and Interferences reversed a rejection of hT2R claims based on later-obtained data that the hT2R sequence in dispute did encode a functional bitter taste receptors, i.e., a human taste receptor that specifically respond to bitter ligands. The reasoning of the Board's reversal of the Examiner's rejections therein are directly on point to the rejections made in the present application" (pg 1).

Applicants' arguments, and the copy of the Board of Appeals Decision in US Serial No. 09/825,882, have been fully considered but are not found persuasive. The fact patterns of the case cited by the Applicant and of the instant rejection are significantly different, and the court decisions are not binding with regard to the instant

Art Unit: 1646

rejections. Specifically, in the 09/825,882 Applicants provided post-filing evidence, considered by the Examiner, "confirming that the methods disclosed in the specification demonstrate that hT2R61 interacts with several compounds that elicit a bitter taste. See the evidence attached to the Appeal Brief as Exhibit 3" (pg 9 of the Decision submitted by Applicants). As noted above, in the instant case the Affidavit submitted by Applicants is missing the referenced Figure 2, and therefore is not considered by the Examiner to confirm that the instant hT2R76 interacts with compound that elicit a bitter taste.

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph, scope of enablement***

Claims 68-92 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention so that it would operate as intended without undue experimentation. This rejection was set forth at pg 4 of the 2/22/06 Office Action.

In the 6/22/06 response, Applicants argue that in view of the functional data provided by the affidavit, and the Board of Appeals decision in US Serial No. 09/825882, the enablement rejection should be withdrawn.

Applicants' arguments have been fully considered but are not found persuasive. For the reasons described above in the section "Claim Rejections – 35 USC § 101", the claimed invention is not supported by a specific and substantial asserted utility, and therefore it is maintained that one of skill would not know how to use the claimed invention without undue experimentation.

Even if the claimed invention was supported by a specific and substantial asserted utility or a well established utility, the claims would still be rejected under 35 U.S.C. 112, first paragraph. This rejection was set forth at pg 4-7 of the 2/22/06 Office Action. It is maintained that the claims lack enablement for the full scope of variant TR76 polypeptides encoded by the nucleic acids encompassed by the claims.

Art Unit: 1646

In the 6/22/06 response, Applicants argue that in view of the functional data provided by the affidavit, and the Board of Appeals decision in US Serial No. 09/825882, the enablement rejection should be withdrawn.

Applicants' arguments have been fully considered but are not found persuasive. First, as noted above, the affidavit submitted by Applicants 9/30/05 is missing Figure 2, and therefore is not considered by the Examiner to confirm that the instant hT2R76 interacts with compound that elicit a bitter taste. Therefore, Applicants' arguments regarding functional data are not considered to be persuasive with regard to the claims that encompass T2R76 variants. Furthermore, as noted above, the fact patterns between the 09/825882 case and the instant case are significantly different, and the court decision with regard to 09/825882 is not binding in the instant case. First, in the 09/825882 case (as noted above) evidence was provided indicating a bitter ligand interacted with T2R61. Second, with respect to variants encompassed by the claims, in the 09/825882 case the claims on appeal were limited to polynucleotides that encode a polypeptide that is 95% or more identical to the polypeptide of SEQ ID NO: 8. In the instant case, the claims encompass polynucleotides that encode polypeptides that are 90% or more identical to the polypeptide of instant SEQ ID NO: 2. Therefore, the instant claims are much broader in scope than those of application 09/825882, and the court decision with regard to those claims is not binding in the instant case.

Therefore, the rejection is maintained for the reasons set forth previously. Applicants' claims encompass a vast number of T2R76 variants, including fragments of SEQ ID NO: 2 of any size. For example, claim 68, part (i) encompasses nucleic acids encoding polypeptides "having at least 90% sequence identity to the polypeptide contained in SEQ ID NO: 2". First, SEQ ID NO: 2 is an amino acid sequence of 318 amino acids. Therefore, the genus of nucleic acids that are at least 90% similar to SEQ ID NO: 2 includes up to 10% of the sequence changed, or up to 31 amino acids changed anywhere in the sequence of SEQ ID NO: 2. Furthermore, the term "contained in SEQ ID NO: 2" is indefinite and therefore has been interpreted to include any shorter sequence "contained" within the longer SEQ ID NO: 2 (See Rejections under 35 USC

112, 2<sup>nd</sup> paragraph, below). Therefore, claim 68 also encompasses nucleic acids encoding any polypeptide fragment of SEQ ID NO: 2 (as well as polypeptides that are 90% similar to these fragments). Furthermore, claim 68, part (iii) is drawn to any nucleic acid sequence that hybridizes to SEQ ID NO: 1 under particular stringent conditions. Such hybridizing fragments would include fragments of any size that are complementary to any shorter sequence within the longer sequence of SEQ ID NO: 1. Furthermore, claim 68, part (iv) is drawn to nucleic acids differing "by at least one functionally equivalent codon". This phrase is used in the specification but is not defined and therefore includes codons that code for different amino acids. Therefore, the claims encompass nucleic acids with an unlimited number ("one or more") of changes to the encoded protein. The claims do include the limitation that the encoded variant bitter taste receptor binds a bitter ligand that specifically binds to T2R76. However, this functional limitation is not sufficient to enable the vast genus of encompassed variants. First, the fact that a bitter ligand can bind a T2R76 variant does not indicate the said variant is functional such that it can be used as SEQ ID NO: 2. For example, a deletion of the internal portion of the protein that interacts with a G protein would still allow the variant to bind an extracellular ligand but would not activate intracellular cell signaling. In order for a variant to be used, it would need to be functional in an assay in which the ligand activates cell signaling. Second, even if such a functional limitation was included, the genus of encompassed molecules is so large that it would require undue experimentation to test and screen each one for activity.

Therefore it is maintained that due to the large quantity of experimentation necessary to generate the large number of variants recited in the claims and possibly screen same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function and the difficulties encountered in screening T2Rs, exemplified by Hoon et al., Chandrashekar et al., and Lindemann (cited in the 3/30/05 Office

Art Unit: 1646

Action), and the breadth of the claims which fail to recite adequate structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope should a substantial utility be established for the claimed polynucleotides.

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph, written description***

Claims 68-92 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection was set forth at pg 7-10 of the 2/22/06 Office Action.

In the 6/22/06 response, Applicants argue that in view of the functional data provided by the affidavit, and the Board of Appeals decision in US Serial No. 09/825882, the written description rejection should be withdrawn.

Applicants' arguments have been fully considered but are not found persuasive. First, as noted above, the affidavit submitted by Applicants 9/30/05 is missing Figure 2, and therefore is not considered by the Examiner to confirm that the instant hT2R76 interacts with compound that elicit a bitter taste. Therefore, Applicants' arguments regarding functional data are not considered to be persuasive with regard to the claims that encompass T2R76 variants. Furthermore, as noted above, the fact patterns between the 09/825882 case and the instant case are significantly different, and the court decision with regard to 09/825882 is not binding in the instant case. First, in the 09/825882 case (as noted above) evidence was provided indicating a bitter tastant ligand interacted with T2R61. Second, with respect to variants encompassed by the claims, in the 09/825882 case the claims on appeal were limited to polynucleotides that encode a polypeptide that is 95% or more identical to the polypeptide of SEQ ID NO: 8. In the instant case, the claims encompass polynucleotides that encode polypeptides that are 90% or more identical to the polypeptide of instant SEQ ID NO: 2. Therefore,



the instant claims are much broader in scope than those of application 09/825882, and the court decision with regard to those claims is not binding in the instant case.

Therefore, the rejection is maintained for the reasons set forth previously. First, as set forth above the evidence (in the form of an affidavit), is not sufficient to demonstrate activation of SEQ ID NO: 2 by PROP (because Figure 2 has not been provided to the Examiner for evaluation). Second, even if this evidence was sufficient to demonstrate activation of SEQ ID NO: 2 by PROP, this functional activity would not be commensurate in scope with the functional limitation recited in the claims. The claims only require "binding" of a ligand to SEQ ID NO: 2, whereas possession of a usable member of the claimed genus requires activation of the receptor. Binding of a ligand to a variant of SEQ ID NO: 2 could occur in the absence of activation. Finally, even if the claims contained a functional limitation related to activation of the receptor, it would not be sufficient to demonstrate possession of the vast genus of polynucleotides encompassed by the instant claims. As set forth in detail above (see the Rejection under 112, 1<sup>st</sup> paragraph, enablement), the genus of claimed polynucleotides comprises polynucleotides encoding polypeptides with an unlimited number of changes to the encoded polypeptide. As set forth previously (3/30/05), although one of skill in the art would reasonably predict that variant sequences exist that retain the functionality of the parent polypeptide, one would not be able make useful predictions as to the nucleotide positions or identities of those sequences based on the information disclosed in the specification.

The instant disclosure of a single polynucleotide, that of SEQ ID NO: 1, encoding a polypeptide with no instantly disclosed specific activities, does not adequately support the scope of the claimed genus, which encompasses a substantial variety of subgenera. A genus claim may be supported by a representative number of species as set forth in *Regents of the University of California v Eli Lilly & Co*, 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation

Art Unit: 1646

of structural features common to the genus, which features constitute a substantial portion of the genus. The instant specification discloses, however, a single isolated polynucleotide sequence SEQ ID NO: 1, which is not sufficient to describe the essentially limitless genera encompassed by the claims.

The specification has not provided a particular essential feature, either a functional or structural feature, that the claimed genus of polynucleotides possesses. The recitation of the property of hybridization does not, alone, provide sufficient information regarding the structure of the claimed polynucleotide variants. Further, most of these variants are expected to encode polypeptides having an amino acid sequence different than that of SEQ ID NO: 2 and thus having different structural and functional properties. Similarly, the recitation of a percent identity to SEQ ID NO: 2 provides no description of any amino acid sequence other than that of SEQ ID NO: 2. The specification has not defined what particular common structural or functional properties are possessed by the claimed genus of polynucleotides. Thus one of skill in the art would appreciate that Applicant was not in possession of the claimed genus of polynucleotides at the time of filing.

The instant claims are not directed to that which is disclosed as essential to the invention, i.e. something that is homologous to the parent SEQ ID NO: 1 and has the function of the parent polynucleotide. Thus, with the exception of the polynucleotide of SEQ ID NO: 1, and other polynucleotides which encode a polypeptide of SEQ ID NO: 2, the skilled artisan cannot envision encompassed variants. Therefore, only a polynucleotides encoding a polypeptide of SEQ ID NO: 2, and polynucleotides consisting of fragments thereof, or polynucleotides consisting of fragments thereof and heterologous sequences (e.g. carrier or tag sequences), but not the full breadth of the claims meet the written description provision of 35 U.S.C. §112, first paragraph.

Claim 92 also lacks written description because the claims encompass T2R nucleic acids of species other than humans, but the specification only provides examples of human T2Rs that are known in the art (page 12). The specification refers to mouse and rat sequences on page 18 but does not provide any specific examples of

T2Rs from species other than humans, or how to identify such sequences through structural features. Thus one of skill in the art would appreciate that Applicant was not in possession of the claimed genus of T2R polynucleotides at the time of filing.

***Claim Rejections - 35 USC § 112, 1st paragraph, new matter***

Claims 77-79 and 81-83 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the claims contain new matter. Each of claims 77-79 and 81-83 was newly submitted 11/8/2005. This rejection was set forth for claims 77-79 and 81-83 at pg 10-11 of the 2/22/06 Office Action.

Applicants' 6/22/06 response does not contain any remarks or arguments directed to this rejection. Therefore, this rejection is maintained for the reasons set forth previously and reiterated herein.

Claim 77 is directed to retroviral vectors comprising an isolated nucleic acid sequence. However, the specification as originally filed does not teach retroviral vectors. The specification on pg 35-36 discusses expression constructs. Representative promoters are taught to include "long terminal repeat promoter from retrovirus" (pg 36, ¶ 93). Suitable vectors are taught to include "viruses such as vaccinia virus or adenovirus" (pg 36, ¶ 94). However, there is no conception of "retroviral vectors" as a particular species of vector of the claimed invention. Therefore, the specification as originally filed lacks support for the genus of molecules encompassed by the claim, nor does the concept of the specific genus flow naturally from the disclosure of the specification. Claims 78 and 81-83 depends from claim 77 and therefore include new matter for the same reason.

Claim 79 is directed to isolated nucleic acids operably linked to a regulatable promoter. However, the specification as originally filed lacks support for a genus of regulatable promoters. The specification (pg 46, ¶ 93) discusses "constitutive promoters" and "inducible promoters". There is no teaching relating to "regulatable promoters". The genus of "regulatable promoters" includes "inducible promoters" but is

Art Unit: 1646

broader because it also encompasses promoters that can be repressed (rather than induced). Therefore, the specification as originally filed lacks support for the genus of molecules encompassed by the claim, nor does the concept of the specific genus flow naturally from the disclosure of the specification. Claim 78 depends from claim 77 and therefore includes new matter for the same reason.

Claim 81 is directed to isolated plasmid comprising a T2R76 nucleic acid and a sequence encoding a G protein. However, the specification as originally filed lacks support for a single plasmid comprising these two nucleic acids. Originally filed claim 23 was directed to a host cell comprising a G protein  $\alpha$  subunit capable of coupling to a T2R76 polypeptide. However, this teaching is broader and encompasses host cells with two separate nucleic acids encoding the T2R76 and the G protein. Nowhere in the originally filed claims or specification is the conception of a single nucleic acid molecule comprising the sequence encoding the T2R76 and G protein. Therefore, the specification as originally filed lacks support for the genus of molecules encompassed by the claim, nor does the concept of the specific genus flow naturally from the disclosure of the specification. Claims 82 and 83 depend from claim 81 and therefore include new matter for the same reason.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph***

Claims 68-92 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection was set forth for claims 68-92 at pg 12 of the 2/22/06 Office Action.

Applicants' 6/22/06 response does not contain any remarks or arguments directed to this rejection. Therefore, this rejection is maintained for the reasons set forth previously and reiterated herein.

Claims 68-72 are indefinite because the metes and bounds of the phrase "contained in" are unclear. For example, it is unclear whether a "polypeptide contained in SEQ ID NO: 2" is limited to a polypeptide consisting of SEQ ID NO: 2, or whether it

Art Unit: 1646

encompasses shorter polypeptides (fragments) that are “contained in” the longer sequence of SEQ ID NO: 2. For purposes of prosecution, this claim has been interpreted broadly to include fragments of SEQ ID NO: 1 or 2.

Claim 70 is indefinite because the metes and bounds of the phrase “a polypeptide having at least 95-99% sequence identity...” are unclear. If this phrase recited “a polypeptide having 95-99% sequence identity...” it would be clear that it encompass a genus limited to 95-99% identity. However inclusion of the phrase “at least” makes it unclear whether or not this genus also includes polypeptides having sequence identity that is greater than 99%. Does a polypeptide that is 99.5% similar meet the definition of “at least 95-99%”?

Claim 77 is indefinite because recites, “The isolated nucleic acid sequence of claim 77 wherein the vector is a retroviral vector.” This is indefinite because the claim depends from itself, and because the term “the vector” lacks antecedent basis. For purposes of prosecution, this claim has been interpreted to depend from claim 75. Applicants are also asked to review claim 78 and confirm that it is intended to depend from claim 77.

The remaining claims are rejected for depending from an indefinite claim.

### ***Claim Rejections - 35 USC § 102***

Claims 68-73 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by WO200257309-A1, Miwa et al, published July 25, 2002. This rejection was set forth at pg 13-14 of the 2/22/06 Office Action.

Applicants' 6/22/06 response does not specifically refer to this rejection. Applicants state only that “As a final note, Applicants advise that a supplemental § 131 Affidavit signed by the inventors excepting Elliot Adler is to be submitted” (pg 1). The Examiner assumes that the § 131 Affidavit referred to by Applicants is in reference to this rejection. However, the Office has not yet received a copy of said supplemental Affidavit. Therefore, the rejection is maintained for the reasons previously set forth; each of claims 68-73 encompasses a polynucleotide as taught by Miwa.

Art Unit: 1646

In the response dated 9/30/05, Applicants submitted an Affidavit signed by Robin Teskin that Applicants argue establishes that Applicants were in possession of the claimed isolated hT2R76 sequence prior to the publication date of the Miwa disclosure. As set forth previously, the affidavit filed on 9/30/05 under 37 CFR 1.131 is ineffective to overcome the Miwa reference. The affidavit is ineffective because it does not meet the requirements of who may make an affidavit or declaration under 37 CFR 1.131. See MPEP 715.04 [R-2], I. WHO MAY MAKE AFFIDAVIT OR DECLARATION, which states,

“The following parties may make an affidavit or declaration under 37 CFR 1.131:

(A) All the inventors of the subject matter claimed.

(B) An affidavit or declaration by less than all named inventors of an application is accepted where it is shown that less than all named inventors of an application invented the subject matter of the claim or claims under rejection. For example, one of two joint inventors is accepted where it is shown that one of the joint inventors is the sole inventor of the claim or claims under rejection.

(C) If a petition under 37 CFR 1.47 was granted or the application was accepted under 37 CFR 1.42 or 1.43, the affidavit or declaration may be signed by the 37 CFR 1.47 applicant or the legal representative, where appropriate.

(D) The assignee or other party in interest when it is not possible to produce the affidavit or declaration of the inventor. *Ex parte Foster*, 1903 C.D. 213, 105 O.G. 261 (Comm'r Pat. 1903).

Affidavits or declarations to overcome a rejection of a claim or claims must be made by the inventor or inventors of the subject matter of the rejected claim(s), a party qualified under 37 CFR 1.42, 1.43, or 1.47, or the assignee or other party in interest when it is not possible to produce the affidavit or declaration of the inventor(s). Thus, where all of the named inventors of a pending application are not inventors of every claim of the application, any affidavit under 37 CFR 1.131 could be signed by only the inventor(s) of the subject matter of the rejected claims. Further, where it is shown that a joint inventor is deceased, refuses to sign, or is otherwise unavailable, the signatures of the remaining joint inventors are sufficient. However, the affidavit or declaration, even though signed by fewer than all the joint inventors, must show completion of the invention by all of the joint inventors of the subject matter of the claim(s) under rejection. *In re Carlson*, 79 F.2d 900, 27 USPQ 400 (CCPA 1935).

The Examiner notes that in the instant case a petition under 37 CFR 1.47(a) (“Filing when an inventor refuses to sign or cannot be reached”) was granted on 3/11/2004 with respect to the inventor Jon Elliot Adler. In view of the granted petition under 37 CFR 1.47(a), and the requirements of part (c) quoted above, the 1.131

Art Unit: 1646

declaration may be signed by the 37 CFR 1.47 applicant or the legal representative, where appropriate (i.e., the 37 CFR 1.47 applicant or the legal representative may sign the 1.131 declaration in place of Jon Elliot Adler).

Therefore, in the instant case, in view of MPEP 715.04(a) and (c) and the granted petition under 37 CFR 1.47(a), a properly executed 1.131 declaration would be signed by each of the Applicants (except Jon Elliot Adler) and the 37 CFR 1.47 applicant or the legal representative for Jon Elliot Adler, unless one of parts MPEP 715.04 (b) or (d) is also met.

### ***Conclusion***

No claims are allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 1646

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

zch

A handwritten signature in black ink, appearing to read "Gary B. Nickol", written in a cursive style.

GARY B. NICKOL, PH.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600